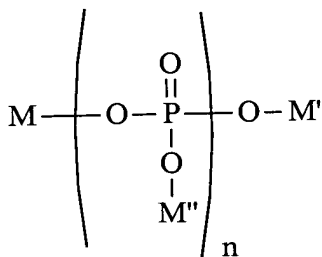


- (a) a beverage composition having a pH of less than about 5; wherein the beverage composition comprises a compound having the structure:



wherein n is an integer averaging from about 7 to about 100 and M, M', and M'' are each, independently, selected from the group consisting of sodium and potassium, and wherein the beverage composition is substantially free of calcium and fluoride and comprises less than about 0.025% of orthophosphate, by weight of the composition; and

- (b) information that use of the beverage composition provides treatment against dental erosion.

#### REMARKS

Applicant thanks the Examiner for the consideration given the present application. Upon entry of the amendments and cancellations herein, Claims 11 - 15, 17 - 20, and 22 remain pending.

Applicant wishes to clarify that all elections of species made, either in writing or by telephone, have been with traverse. In this regard, Applicant directs the Examiner to page 2 of the Office Action dated June 4, 2001 which lists Applicant's election (sodium hexametaphosphate (n = 21), beverages containing fruit juice, carbohydrate sweeteners (as high fructose corn syrup or sugar), and substantially free of calcium and fluoride. As is set forth on page 8 of Applicant's response dated April 23, 2001, this election was made *with traverse*.

In order to simplify the legal issues in the present Application, Claims 1 - 5, 7 - 10, and 21 have been cancelled herein without prejudice. Applicant fully intends to file a continuing application directed to the subject matter of these cancelled claims and asserts that such cancellation should not in any way be construed against Applicant. In view of the present cancellations, Applicants have amended the title of the specification to be more specifically descriptive of the presently pending claims; no new matter is added through this amendment.

As has been established in the present specification, and has been declared in the specification by Applicant (the inventor), the present dental erosion benefit is a result of the polyphosphate specified in the claims rather than any orthophosphate. In support of this establishment, Claim 11 has been amended to recite compositions comprising less than about 0.025% of orthophosphate, by weight of the composition. Support for this amendment is found in

Applicant's specification at page 6, line 28 through page 7, line 5 and page 7 lines 12 – 17. No new matter is introduced through the presently amended claims.

Applicants also note that the present Continuing Prosecution Application is being filed in order to submit a Supplemental Information Disclosure Statement. This Statement is being filed concurrently with the present amendment.

*The Rejections Under 35 U.S.C. §§ 102(a), 102(b), 102(e), and 103(a)*

The Examiner has rejected Claims 1 – 5, 7 – 15, and 17 – 22 under 35 U.S.C. §§ 102(a), 102(b), and 102(e) as being anticipated by mere recitation of a condensed phosphate or polyphosphate salt in low pH beverages in any of the various patents cited by the Examiner on Form PTO-892. Applicant notes that Claims 1 – 5, 7 – 10, and 21 have been cancelled without prejudice; accordingly, remaining Claims 11 – 15, 17 – 20, and 22 are addressed against the Examiner's rejections herein.

It is unclear to Applicant whether the rejection presented by the Examiner based on inherency was directed only against the presently cancelled method of use claims or the presently pending kit claims as well (Claims 11 – 15, 17 – 20, and 22). For purposes of this reply, and ensuring a complete response herein, Applicants will assume *arguendo* that the Examiner directed the rejection based on inherency against all claims pending at the time of the Office Action, including the kit claims (Claims 11 – 15, 17 – 20, and 22).

Applicants assert that any rejection of Claims 11 – 15, 17 – 20, and 22 under 35 U.S.C. §§ 102(a), 102(b), and 102(e), based on inherency and in view of any of the U.S. Patents cited on Examiner's Form PTO-892, is untenable and should be withdrawn. These kit claims are not anticipated based on inherency because each and every element of the claims is not disclosed in any of the cited patents, either expressly or inherently. See *Verdegaal Bros. v. Union Oil Co.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Indeed, a key limitation of kit Claims 11 – 15, 17 – 20, and 22 is "*information* that use of the [recited] beverage composition provides treatment against dental erosion." This limitation (the *information* in association with the recited composition) is not taught, suggested, or even inherently present in any of the cited patents. Moreover, there is no extrinsic evidence which may be used to show that the missing descriptive matter is necessarily, or even possibly, present in the cited patents. See *Continental Can Co. v. Monsanto Co.*, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991). Accordingly, the cited case law of *Atlas Powder* and *Ex parte Novitski* is irrelevant in view of the presently pending claims, as there is *no inherent presence of the claimed subject matter* set forth in the patent references presented by the Examiner. Any rejection of Claims 11 – 15, 17 – 20, and 22 based on inherency is therefore misplaced and should be withdrawn. If the Examiner persists with an inherency rejection in view of these kit claims, Applicant respectfully requests that the Examiner make clear the specific disclosure which renders the claims inherent and the specific

rationale relating to applicability of *Atlas Powder* and *Ex parte Novitski*, specifically given that the recited *information* cannot be an inherent feature of the previously described compositions.

Applicant also respectfully traverses the rejection of Claims 11 – 15, 17 – 20, and 22 in view of any of the various U.S. patents cited by the Examiner on Form PTO-892 based on *In re Haller*, 73 USPQ 403 (CCPA 1947). The Examiner has cited *Haller* for the premise that “novelty cannot be predicated on printed instructions.”

However, as reiterated in Applicant’s telephone interview with the Examiner, Applicant traverses this rejection and the Examiner’s reliance on *Haller*. Indeed, in the more contemporary cases *In re Miller*, 164 USPQ 46 (CCPA 1969) and *In re Gulack*, 217 USPQ 401 (Fed. Cir. 1983), which were both subsequent to *Haller*, articles comprising previously known compositions, in association with information which was functionally related to such composition, were held novel and non-obvious over the known compositions. For example, in *Miller*, which related to printed information on a measuring device, the Court stated:

[The Examiner’s] characterization of printed matter as “unpatentable” is beside the point; no attempt is here being made to patent printed matter as such. The fact that printed matter by itself is not patentable subject matter, because non-statutory, is no reason for ignoring it when the claim is directed to a combination. Here there is a new and unobvious functional relationship between a measuring receptacle, volumetric indicia thereon . . . and a legend indicating the ratio, and in our judgment the appealed claims properly define this relationship.

See Miller, at third paragraph from conclusion of opinion (emphasis added).

Indeed, the PTO supports *Miller*, and *only* directs claim rejections in view of 35 U.S.C. 101 and *Miller* when a mere arrangement of printed matter is claimed. See MPEP 706.03(a).

The Federal Circuit affirmed Miller in Gulack, even while recognizing that the “sole difference” between the claimed article and the prior art composition was the printed material. In *Gulack*, the Federal Circuit stated:

A functional relationship of the precise type found by the CCPA in *Miller* – to size or to type of substrate, or conveying information about [the] substrate – is not required. What is required is the existence of differences between the appealed claims and the prior art sufficient to establish patentability.

See Gulack, Section II, B.

Taken in the context of the present invention, Claims 11 – 15, 17 – 20, and 22 are indeed patentable over the cited U.S. patents. The information referred to in independent Claim 11, i.e., information that use of the beverage composition provides treatment against dental erosion, is clearly functionally related to the beverage composition itself. It is representative of the present

discovery that the polyphosphate compounds recited in the claims are surprisingly effective against dental erosion. Moreover, the kits of Claims 11 – 15, 17 – 20, and 22 are directive, such that a consumer will understand the present discovery and have the ability to capitalize on such discovery. Thus, the utility of the present compositions is furthered because the consumer will understand the benefits, and be encouraged to utilize, the beverage composition based on this surprising and previously unknown use.

Applicant asserts that there are indeed differences between the cited art and the presently claimed kits, rendering the kits novel and unanticipated under 35 U.S.C. § 102. Like *Gulack* and *Miller*, the differences are largely related to the *information*. Moreover, this information is functionally related to the beverage of the recited kits (as highlighted in *Gulack*, yet “not required” under *Miller*). This information is a reflection of the present discovery that the recited compositions are surprisingly useful against dental erosion; Applicants have a legal right to protect this novel discovery. Applicant finds nothing in *Gulack* and *Miller* that should preclude Applicant from this legal right, and the Examiner has not provided guidance with regard to any rationale to the contrary. Applicant therefore strongly asserts that the Examiner should withdraw the rejection under 35 U.S.C. §§ 102(a), 102(b), and 102(e), and allow the claims as pending.

Notwithstanding, the Examiner makes the blanket statement that it is the PTO’s position to distinguish *Miller/Gulack* in favor of *Haller*, based on the facts of the present application. In doing so, the Examiner fails to provide Applicant with any rationale, explanation, or guidance for this “official” position. The Examiner fails to guide Applicant as to why *Haller* should be followed based on the present circumstances, and why *Miller/Gulack* should not be followed. Accordingly, if the Examiner persists in the present rejection, as based on an application of *Haller*, Applicant respectfully requests that the Examiner explain a specific and clear rationale of the basis of the rejection and choice of law.

Additionally, similar to the reasons stated above, Applicant further asserts that the kits of Claims 11 – 15, 17 – 20, and 22 would have been non-obvious over the cited references. In particular, the Examiner has combined any of the various patents cited by the Examiner on Form PTO-892 in view of each of Shibata *et al.*, “Antibacterial Action of Condensed Phosphates on the Bacterium *Streptococcus Mutans* and Experimental Caries in the Hamster,” *Archives of Oral Biology*, Vol. 27, pp. 809 – 816 (1982) (herein referred to as Shibata *et al.*) or McGaughey *et al.*, “Effects of Polyphosphates on the Solubility and Mineralization of HA: Relevance to a Rationale for Anticaries Activity,” *Journal of Dentistry Research*, Vol. 56, No. 6, pp. 579 – 587 (June 1977) (herein referred to as McGaughey *et al.*) and each of previously cited Muhler and McDonald *et al.*

To establish obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success in making the modification. Finally, the prior art reference must

teach or suggest all the claimed limitations and the reasonable expectation of success must both be found in the prior art and not based on Applicants' disclosure. See In re Vaeck, 20 USPQ2d 1438 (Fed. Cir. 1991).

For the reasons stated above and as supported by established law, it would have been non-obvious to one of ordinary skill to use the recited polyphosphate compositions to treat dental erosion and to therefore provide kits which disseminate information regarding such treatment. Applicant asserts that, while the cited U.S. patents collectively disclose the polyphosphate compound utilized in the present claims, the patents fail to disclose, teach, or even suggest any use against dental erosion. Moreover, these references fail to suggest that the presently recited polyphosphate compounds would be useful as a substitute for the monosodium dihydrogen phosphate ("MDP",  $\text{NaH}_2\text{PO}_4$ ) of Muhler and McDonald *et al.* for the purpose of treating dental erosion. Indeed, Applicant has amended independent Claim 11 to require that the claimed beverage composition comprises less than about 0.025% of orthophosphate (*i.e.*, MDP), by weight of the composition. This is reflective of Applicant's unique and surprising discovery that the recited linear polyphosphates have effective utility against dental erosion.

Shibata *et al.* and McGaughey *et al.* recite the use of condensed phosphates *at elevated pH in the diet for treatment of caries, not dental erosion*. However, as claimed, the present kits comprise beverage compositions having a pH of less than about 5. It is well-known in the art that acidic compositions are actually considered to exacerbate dental erosion (which occurs by direct action of acid on the enamel surface). See specification at page 1 and Lussi *et al.*, "Prediction of the Erosive Potential of Some Beverages", *Caries Research*, Vol. 29, pp. 349 – 354 (1995), which examined the erosive potential of many beverage compositions, all having a pH of less than 5.

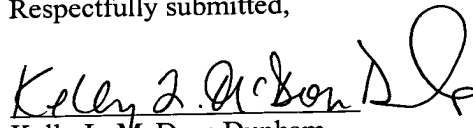
Taken together, therefore, the Examiner's cited combination of references fails to teach or even suggest the presently claimed kits. Firstly, and following the dictates of the law regarding non-obviousness, there would have been no motivation or suggestion in the references to make any modification which would arrive at the present kits. The present kits claim beverage compositions having acidic pH and comprising the defined linear polyphosphates and explicitly less than about 0.025% orthophosphate, all together with information that these acidic beverage compositions provide treatment against dental erosion. This is unexpected in light of the combined references, and in view of the literature generally, which would preclude any motivation to modify. Secondly, but similarly, there would have been no reasonable expectation of success for the same foregoing reasons. Finally, *the combination of references fails to teach or suggest all of the claimed limitations*, particularly with regard to the definition of the linear polyphosphate compound, the acidity of the beverage composition, and the surprising information associated therewith. Respectfully, the Examiner has therefore failed to establish any obviousness of the presently claimed kits.

For all of the foregoing reasons, Applicant therefore asserts that the claimed kits are indeed novel and non-obvious over the cited references and in view of the consistent controlling authority. Applicant therefore requests that the Examiner withdraw the rejections and promptly allow the claims as amended herein.

#### CONCLUSION

For all of the above reasons, and in view of the amendments and cancellations herein, it is respectfully requested that the Examiner withdraw the rejections under 35 U.S.C. §§ 102(a), 102(b), and 102(e), and 103(a) and allow Claims 11 – 15, 17 – 20, and 22 as pending herein. If the Examiner believes that personal contact would be advantageous to the disposition of this case, he is respectfully requested to contact the undersigned at his earliest convenience.

Respectfully submitted,



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Registration No. 43,787

September 26, 2001  
Cincinnati, Ohio  
Tel: 513-634-0102

*Version with Markings to Show Changes Made*

The title of the specification has been amended as follows:

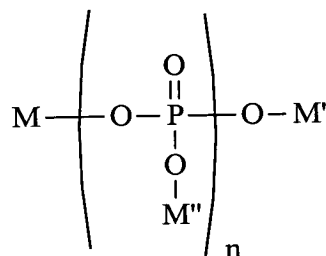
KITS COMPRISING A BEVERAGE COMPOSITION AND INFORMATION FOR  
USEMETHODS OF USING A BEVERAGE COMPOSITION

Claims 1 – 5, 7 – 10, and 21 have been cancelled without prejudice.

Claim 11 has been amended as follows:

11. (Twice Amended) A kit comprising:

- (a) a beverage composition having a pH of less than about 5; wherein the beverage composition comprises a compound having the structure:



wherein n is an integer averaging from about 7 to about 100 and M, M', and M'' are each, independently, selected from the group consisting of sodium and potassium, and wherein the beverage composition is substantially free of calcium and fluoride and comprises less than about 0.025% of orthophosphate, by weight of the composition; and

- (b) information that use of the beverage composition provides treatment against dental erosion.